REMARKS

In the Office Action, claims 33-36 are rejected under 35 U.S.C. §102 or §103 as allegedly unpatentable over U.S. Patent No. 4,443,441 (Galin). Applicant believes that the rejections should be withdrawn at least in view of the reasons set forth below.

Of claims 33-36, claim 33 is the sole independent claim which recites an ophthalmic formulation in aqueous solution for topical administration including a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. The claimed ophthalmic formulation with active phentolamine compound can effectively reduce pupil size in dim light to improve vision in dim light and further minimize redness in the eye upon use. Indeed, Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision by reducing pupil size in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Specification, Examples 1 and 2; Tables 1 and 2; and corresponding text.

In direct contrast, Galin indicates that "...the smaller pupil reduces vision, particularly in dim light." See, Galin, col. 1, lines 37-38. Further, from a list of at least six possible active agents, the preferred and only working example in Galin is directed to a solution that contains thymoxamine, and thus, the improved effect of a phentolamine-based solution on vision in dim light as claimed should not be deemed an inherent property of the Galin solution. Indeed, Galin is directed to the use of alpha adrenergic blocking agents to aid in the fixation of intraocular lenses (See, Galin, col. 1, lines 4-5) and not the effective reduction of pupil size to improve vision in dim light as claimed.

Again, the claimed ophthalmic formulation includes a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. As previously discussed, Applicant has demonstrated that a phentolamine-based formulation has enhanced effects on pupil reduction than other types of alpha 1 antagonist-based formulations, thus improving vision in dim light due to enhanced pupil reduction. Such unexpected results as embodied by the claimed invention are further supported by the Affidavit of Gerald Horn, M.D dated October 28, 2007

(Affidavit) as previously submitted in this case along with Applicant's Response dated April 15, 2008, another copy of the Affidavit is submitted herewith as Exhibit I for convenience. See Affidavit, for example, on pages 1 and 2, at paragraph 4:

> [t]he claimed phentolamine-based formulation inhibits pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Therefore, pupil size is optimized to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. Moreover, this result was unexpected since conventional ophthalmology indicated that reducing pupil size in dim light would cause vision acuity to deteriorate.

Contrary to the Patent Office position, Galin fails to recognize the claimed ophthalmic formulation with phentolamine in a therapeutically effective amount thereby effectively reducing pupil size to improve vision in dim light as claimed and as previously discussed. Again and in direct contrast, Galin indicates that "...the smaller pupil reduces vision, particularly in dim light". Therefore, Applicant does not believe Galin provides sufficient teaching to render unpatentable the phentolamine-based ophthalmic solution that improves vision in dim light as presently claimed, and thus, the anticipation and obviousness rejections in view of Galin should be withdrawn. The Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

For the foregoing reasons, Applicant respectfully submits that the present application is in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

K&L Gates LLP

BY _____

Thomas C. Basso
Reg. No.: 46,541
Cust. No. 24573

Dated: 6/6/11

Exhibit I

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Gerald Horn
Appl. No.:	09/854,414
Conf. No.:	7675
Filed:	May 10, 2001
Title:	OPHTHALMIC FORMULATIONS
Art Unit:	1618
Examiner:	Z. Ray
Docket No.:	114309-1007

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AFFIDAVIT OF GERALD HORN, M.D.

I, Gerald Horn, hereby states as follows:

1. I am the sole inventor of the above-referenced U.S. Patent Application No. 09/854,414.

2. I have reviewed the Final Office Action issued on September 11, 2007 regarding this case, a copy of which is attached herewith as Exhibit A. In particular, I have reviewed U.S. Patent No. 4,443,441 (Galin) as referenced in the Final Office Action on page 2, a copy of which is attached herewith as Exhibit B.

3. Of the presently pending claims, claim 74 is the sole independent claim. Claim 74 is directed to an ophthalmic, night vision formulation. The formulation includes a sterile aqueous carrier; and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount so as to effectively disrupt endogenous compounds which stimulate dilator muscles of a human eye thereby effectively reducing pupil size to improve night vision.

4. The claimed phentolamine-based formulation inhibits pupillary dilation in scotopic conditions preferentially over constriction of the pupil, affecting the dilator muscles of the iris preferentially, and has no clinically significant effect on the ciliary muscle responsible for accommodation. Therefore, pupil size is optimized to obtain enhanced vision acuity in dim light (e.g., at night) by reducing the pupil diameter in dim light. Moreover, this result was unexpected

since conventional ophthalmology indicated that reducing pupil size in dim light would cau vision acuity to deteriorate.

5. I also conducted experiments that demonstrated the beneficial effects of t phentolamine-based formulation as claimed. For example, Table 1 on page 27 of the pres application indicates that the phentolamine-based formulation demonstrates enhanced pu reduction effect while minimizing eye redness as compared to other types of alpha-1 antagon based formulations. Further, Table 2 on page 28 of the present application demonstrates t beneficial effects on night vision by reducing the pupil diameter in dim light. In Table 2, t glare and halo effects were reduced in addition to an improvement in depth perception reducing the pupil diameter in dim light.

6. In contrast, Galin is directed to the use of alpha adrenergic blocking agents to a in the fixation of intraocular lenses. See, Galin, col. 1, lines 4-5. Indeed, Galin further disclos that this type of pupillary activity can reduce eccentric synechia formation and lens dislocatio See, Galin, column 1, line 61-67. Nowhere does Galin suggest that the reduction of pupil size dim light can enhance night vision in contrast to the claimed phentolamine-based formulatio Again, the reduction of pupil size to enhance night vision was contrary to convention ophthalmology as previously discussed. Moreover, nowhere does Galin suggest that phentolamine-based formulation has enhanced effects on pupil reduction in dim light, th enhancing night vision, as compared to other types of formulations. Indeed, the only workin example in Galin relates to a thymoxamine-based formulation to aid in the fixation of intraocular lens.

I hereby declare that all statements made herein of my own knowledge are true and th all statements made on information and belief are believed to be true, and further that thes statements were made with the knowledge that willful false statements may jeopardize th validity of the application or any patent issued thereon.

Date: October 28, 2007

GERALD HORN, M.D.